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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,282	12/06/2001	Thomas W. Konowalchuk	LFT000 CIP3	4202

7590 05/22/2002
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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/016,282

Applicant(s)

KONOWALCHUK ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

This is a continuation-in-part of a US application 09/795,279.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression, "a method for preventing lesions caused by a virus of Herpesviridae or Poxviridae..." in claim 1, line 1-2, renders the claims indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. Examples of how and when to prevent viral lesions caused by are not set forth in the specification. Absent such exemplification, the skilled artisan could not establish the identity of those situations wherein prevention of viral lesions caused by virus of Herpesviridae or Poxviridae would be effected. Furthermore, it is unclear as to the degree of prevention (e.g., total prevention, some prevention, probable prevention, total prevention in most cases...etc.) herein because the specification does not disclose the extent of prevention achieved. Examiner would favorably consider the term "prophylaxis" over "prevention".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pamukoff (Canadian Patent: CA 1221640 from the Information Disclosure Statement received December 6, 2001), Poli et al. (Food Chemistry 1979; 4:250-258 from the Information Disclosure Statement received December 6, 2001), Bhatia et al. (Indian Journal of Animal Sciences 1998; 68(6): 518-520 from the Information Disclosure Statement received December 6, 2001), and Simmons et al. (US Patent 5,405,602).

Pamukoff teaches a 1-10% ethyl alcohol containing topical composition for treating viral infections broadly, in particularly the infections that are caused by Herpes virus such as Herpes Simplex 1, Herpes Simplex 2, and common cold viruses (See particularly page 2, first paragraph; also page 7-9, Examples 2-5; also claims 1 and 2). Pamukoff also teaches that their antiviral composition can be formulated into creams (See particularly page 2, line 3).

Poli et al. teaches that glycolic acid is virucidal against herpevirus (See particularly page 253, Table 1). Poli also teaches that the acid is in 0.1M concentration (See page 252, second paragraph). 0.1M of glycolic acid (Molecular Weight = 76g) is equal to 0.76 % wt.

Bhatia et al. teaches that 0.4% of hydrochloric acid is effective to inactivate goat-pox virus which is in the Poxviridae family (See particularly the abstract; also page 519,

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col. 1, Table 1 and col. 2, third paragraph). Bhatia also teaches that some strains of pox viruses are more sensitive to acidic pH: such as pH of 3 (See page 519, second to last paragraph).

Simmons teaches that 1,4-butanediol is useful in an antiviral method against HIV infection (See particularly claim 1).

The references do not expressly teach the employment of 1-10% ethyl alcohol or 1,4-butanediol and glycolic acid or hydrochloric acid into the same method of inactivating viruses. The references do not expressly teach the composition pH to be 2.45. The references do not expressly teach the weight ratio of glycolic acid as 0.6%. The references do not expressly teach the method of inactivating molluscum contagiosum.

It would have been obvious to one skill in the art when the invention was made to employ 0.6% of glycolic acid or hydrochloric acid and 1-10% ethyl alcohol or 1,4-butanediol: and adjust the final pH to 2.45, in a method of inactivating viruses, thereby preventing lesion formation;including molluscum contagiosum.

One of ordinary skill in the art would have motivated to employ 0.6% of glycolic acid or hydrochloric acid and 1-10% ethyl alcohol or 1,4-butanediol and adjusted the final pH to 2.45 in a method of inactivating viruses, and prevent lesion formation thereby, including molluscum contagiosum because employing two or more agents which are known to be useful to inactivating viruses individually in the same method for the very same purpose is *prima facie* obvious. See *In re Kerkhoven* 205 USPQ 1069. Furthermore, the optimization of therapeutic effect parameters (e.g., pH and amount of

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the active) is obvious as being within the skill of the artisan. Possessing the cited prior art teaching, the skilled artisan would have known that certain pox viruses are more sensitive to acidic pH. In addition, hydrochloric acid is known to be useful in inactivating goat-pox virus. Therefore, employing hydrochloric acid containing composition in a method to inactivate other poxviruses including molluscum contagiosum would have been reasonably expected to be similarly effective.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
May 20, 2002


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200